

Application No.: 09/333,256
Attorney Docket No.: 017094-0260218

REMARKS

I. Status of the claims

Claims 1-6 are pending in this application. Claim 4 has been amended to correct a typographical mistake.

II. Claim objection

Claim 4 was objected to because of the phrase "cornstarch talc." Per the examiner's suggestion, this phrase has been amended to "cornstarch, talc."

III. Rejection of claims 2 and 4-6 under 35 U.S.C. § 112, first paragraph

The examiner has rejected claims 2 and 4-6 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. For claim 2, the examiner has alleged that the specification does not provide support for the limitation, "as a dry binder nonpreswollen cornstarch or microfine cellulose." For claims 4-6, the examiner has alleged that the specification does not provide support for the specific weight ratios of lactose monohydrate, microfine cellulose, nonpreswollen cornstarch, talc, highly disperse silica, and magnesium stearate. Applicants respectfully disagree.

Support for each of these claim elements may be found in the original claims of the application. Since the original claims are considered part of the application, they sufficient support these elements. Accordingly, Applicants respectfully request that the examiner withdraw these rejections.

IV. Rejection of claims 1-6 under 35 U.S.C. § 112, first paragraph

The examiner has rejected claims 1-6 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. Referencing examples 2 and 3, the examiner alleges that in order to obtain a stable dosage form without the use of preswollen starch, the claimed invention requires specific film coating polymer in a specific amount. Applicants respectfully traverse this rejection.

One skilled in the art would be able to prepare a film-coated tablet in accordance with the claimed invention without undue experimentation. While a skilled artisan would look to the

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examples as guidance when preparing the film-coated tablet, the claimed invention should not be limited to the examples and the specific amounts used in the examples. Rather, the test for enablement is whether the skilled artisan can practice the claimed invention without undue experimentation. The specification provides sufficient details regarding the preparation of this film-coated tablet, that a skilled artisan would be able to practice the claimed invention without undue experimentation. Accordingly, Applicants respectfully request that the examiner withdraw this rejection.

V. Rejections under 35 U.S.C. § 103(a)

The examiner has rejected claims 1-6 under 35 U.S.C. § 103(a) as being unpatentable over the Rote Liste (Cyclo-cell) document ("Rote Liste") in view of U.S. Patent No. 5,922,727 to Cho et al. ("Cho"). The examiner has also rejected claims 1-6 under 35 U.S.C. § 103(a) as being unpatentable over Rote Liste in view of U.S. Patent No. 5,358,718 to Sauerbier et al. ("Sauerbier"). Applicants respectfully traverse these rejections.

The examiner bases both of these rejections on Rote Liste, which teaches a composition that uses cornstarch. One skilled in the art would have understood the Rote Liste disclosure relating to cornstarch to mean a preswollen cornstarch. Since Applicants' claimed invention recites a film-coated tablet that does not contain preswollen starch, Rote Liste does not teach or suggest Applicants' claimed invention.

Furthermore, neither Cho nor Sauerbier cure the deficiencies of Rote Liste. There is no disclosure in Cho or Sauerbier that would motivate a skilled artisan to substitute the preswollen starch disclosed in Rote Liste for a non-preswollen starch.

Accordingly, Applicants respectfully request that the examiner withdraw these rejections.

VI. Conclusion

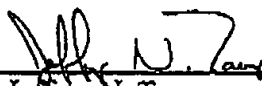
Applicants believe that the amendments and remarks place the application in condition for allowance, and respectfully request that the examiner issue a Notice of Allowance on the pending claims.

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Should any issues remain unresolved, the examiner is encouraged to contact the undersigned attorney for Applicants at the telephone number indicated below in order to expeditiously resolve any remaining issues.

Respectfully submitted,

PILLSBURY WINTHROP LLP

By: 
Jeffrey N. Townes
Registration No. 47,142

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Pillsbury Winthrop, LLP
1600 Tysons Boulevard
McLean, VA 22101
703.905.2000 Telephone
703.905.2500 Facsimile